REMARKS

Claims 1-3, 5, 6, 8, 10, 11, 14–17 are pending in the application. Claim 4, 7, 9 12 and 13 have been canceled. Claims 1, 2, 8 and 11 have been amended above based on the Specification as originally filed. No new matter has been added.

Rejections under 35 USC 102(b)

1. Claims 1-3 and 5-17 stand rejected under 35 USC 102(b) as being anticipated by Niehoff.

It is well settled that in order for a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in prior art. The disclosure requirement under 35 USC 102 presupposes knowledge of one skilled in art of claimed invention, but such presumed knowledge does not grant license to read into prior art reference teachings that are not there. See *Motorola Inc. v. Interdigital Technology Corp*. 43 USPQ2d 1481 (1997 CAFC). It is also well-settled that a 35 USC 102 rejection must rest upon the literal teachings of the reference and that the teachings must disclose every element of the claimed invention in as complete detail as is contained in the claim (See. *Jamesbury Corp v. Litton Industrial Products, Inc.* 225 USPQ, 253, 256 (CAFC 1985); *Kalman v. Kimberly-Clark Corp* 218 USPQ 781, 789 (Fed. Cir. 1983)).

The Office Action alleges that: "The empty syringe is filled by retraction of the plunger while the interior of the syringe communicates with a supply of the contrast fluid via an injection tube connected between the nozzle of the syringe and the supply of media. Then, bubbles are removed from the syringe, and the injection is performed. At the end of the procedure, the syringe plunger typically is forward, as is the plunger drive. "

Claim 1 has been amended to include "in response to sensing the syringe, automatically advancing the piston of the injector to engage the plunger of the syringe and to advance the plunger to the distal end thereof."

Applicants' invention includes as a non-limiting example that:

> When attaching syringe 12 to the mounting assembly 14, if syringe 12 is rotated after tabs 30 engage ledge 29, a sensor 50 is provided in annular surface 28 to read the encoding device 48. Sensor 50 then forwards the associated signals to injector controller 51, which interprets the signals and modifies the function of the injector 20 accordingly. Examples of the information which could be encoded on encoding device 48 include dimensions of syringe 12, volume of syringe 12, content of syringe 12 (in the case of a pre-filled syringe), manufacturing information such as lot numbers, dates and tool cavity number, recommended contrast media flow rates and pressures, and loading/injection sequences. (Specification, page 19, para 2)

Niehoff discloses a computer controlled injector that includes "a sensor which detects the location of the plunger drive jaw 20, which is coupled directly to and moves the plunger" (Col. 3, lines 54-58). Thus, Neihoff discloses a sensor that only tracks the physical movement of plunger.

Further, Applicants' invention includes:

> The "auto engage" feature allows an injector to automatically advance the drive piston thereof to engage a syringe plunger upon installation or attachment of the syringe to the injector. In a preferred embodiment, the auto engage feature occurs without operator intervention. This feature is particularly useful for preloaded and prefilled syringes, which typically have plungers located at some position within the syringe barrel other than at the proximal and distal ends thereof, and plunger-forward syringes. In the case of prefilled syringes, the auto engage feature automatically connects the injector piston and syringe plunger for subsequent priming of the syringe (and associated tubing) and subsequent injection. For plunger-forward syringes, the auto engage feature engages the piston and plunger for subsequent retraction of the plunger for aspiration of fluid, such as contract media, into the syringe. (Specification, page 57, para 2).

Claim 8 is also directed to the method and has been amended to include "automatically determining based on the sensing whether the syringe is an empty syringe, a preloaded syringe or a prefilled syringe" and automatically advancing and retracting the piston.

Applicants invention includes these novel features, for an example that is non-limiting:

> "[t]he "auto advance" feature is related to, and may be considered a type or subset of, the auto engage feature. The auto advance feature allows an injector to automatically advance the plunger of a plunger rearward syringe (i.e., by the drive piston of the injector) to the distal end of the syringe after the syringe is installed on the injector. This feature operates to expel air from an empty, plunger-rearward syringe and to place the syringe plunger in a position to be subsequently retracted to aspirate fluid, such as contrast media, into the syringe for an injection procedure. In a preferred embodiment, the injector senses the mounting or installation of the syringe thereon and automatically advances the piston without operator intervention to drive the plunger to the distal end of the syringe. Of course, this feature would ordinarily be used only with empty syringes (as compared to preloaded or prefilled syringes) to prevent fluid from being expelled therefrom. (Specification, page 57, para 3 to page 58).
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> The "auto fill" or "auto load" feature allows an injector to automatically retract a syringe plunger (i.e., by means of the injector piston) to draw in or aspirate a programmed amount of fluid, such as contrast media, into the syringe. Preferably, the auto fill feature occurs without operator intervention, thereby allowing the operator to perform other tasks (e.g., programming the scanner or injector, positioning the patient on the scanner table, catherizing the patient) while the syringe is being filled with fluid. Of course, this feature typically is not necessary for prefilled or preloaded syringes, which already contain fluid therein. (Specification, page 58, para 3 to page 59, line 2).
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> As will become apparent, the auto prime feature may be functionally dependent, in certain respects, on the auto fill feature described above. When a syringe is filled with fluid (i.e., by means of the auto fill feature), the injector automatically compensates for the connector tube by adding its corresponding fluid volume to the fluid volume desired by the operator to be aspirated into the syringe for an injection operation. For example, if the operator desires to fill the syringe with 150ml of fluid for an injection procedure, the auto fill feature will compensate for the connector tube fluid volume by automatically adding 2.78 ml of fluid (e.g., for a 60' LPCT), for a total volume of 152.78 ml aspirated into the syringe. After the syringe is filed with fluid, the auto prime feature would then cause the injector piston to advance the syringe plunger to the extent necessary to expel air from the syringe and connector tube system, preferably without prompting by the operator. Once the auto prime function is conducted, fluid should be present at the patient end of the connector tube (i.e., the end that is connected to the

catheter). (Specification, page 59, para 3).

As can be appreciated, the auto prime feature may save operator time and reduce the amount of wasted fluid. By automatically compensating for the fluid contained within the connector tube, the operator does not have to vigilantly watch the progression of the fluid from the syringe through the connecting tube in order to stop the advancement of the piston before a significant amount of fluid is discharged from the end of the connector tubing. Also, because some operators of conventional injectors advance the piston quickly to lessen the time required to prime the syringe and tubing system, often a significant amount of fluid will be expelled from the end of the connector tubing before the operator stops the piston's advancement. If a sufficient amount of contrast is expelled, the syringe may have to be re-filled (and the syringe and tubing system subsequently re-primed) to insure that it contains a sufficient amount of fluid for the required injection procedure. (Specification, page 59, para 3 to page 60, para 1)

Claim 11 also directed to the method and has been amended to include "advancing the piston to prime the syringe and a tube connected to the syringe, wherein the priming is based on a fluid volume of the tube."

Applicants' invention includes:

[t]he "auto prime" feature allows an injector to automatically prime the fluid path (i.e., syringe and connecting tubing) before an injection procedure. Preferably, the volume of fluid contained within a connector tubing used with a syringe is pre-programmed into the injector. For example, a 60' low pressure connecting tubing ("LPCT") provided by Medrad, Inc., the Assignee of the present application, for use with its disposable syringes typically holds approximately 2.78 ml of fluid. Alternately, the operator may manually program the fluid volume contained within the connector tube into the injector.

As will become apparent, the auto prime feature may be functionally dependent, in certain respects, on the auto fill feature described above. When a syringe is filled with fluid (i.e., by means of the auto fill feature), the injector automatically compensates for the connector tube by adding its corresponding fluid volume to the fluid volume desired by the operator to be aspirated into the syringe for an injection operation. For example, if the operator desires to fill the syringe with 150ml of fluid for an injection procedure, the auto fill feature will compensate for the connector tube fluid volume by automatically adding 2.78 ml of fluid (e.g., for a 60' LPCT), for a total volume of 152.78 ml aspirated into the syringe. After the syringe is filed with fluid, the auto prime feature would then cause the injector piston to advance the syringe plunger to the extent necessary to expel air from the syringe and connector tube system, preferably without prompting by the operator. Once the auto prime function is conducted, fluid should be present at the patient end of the connector tube (i.e., the end that is connected to the catheter).

As can be appreciated, the auto prime feature may save operator time and reduce the amount of wasted fluid. By automatically compensating for the fluid contained within the connector tube, the operator does not have to vigilantly watch the progression of the fluid from the syringe through the connecting tube in order to stop the advancement of the piston before a significant amount of fluid is discharged from the end of the connector tubing. Also, because some operators of conventional injectors advance the piston quickly to lessen the time required to prime the syringe and tubing system, often a significant amount of fluid will be expelled from the end of the connector tubing before the operator stops the piston's advancement. If a sufficient amount of contrast is expelled, the syringe may have to be re-filled (and the syringe and tubing system subsequently re-primed) to insure that it contains a sufficient amount of fluid for the required injection procedure.

While the auto prime feature is preferably intended for use with empty syringes that have been filled with fluid by an aspiration procedure on the injector (i.e., non-prefilled and non-preloaded syringes), the auto prime feature could also be used with prefilled and preloaded syringes. (Page 59, Para 3 to page 60, para 2).

Niehoff is directed to an injector including a plunger drive controller that has a locked mode in which motion, initially requested by pressing a manual movement switch, will continue whether or not the operator continues pressing the switch, until the plunger drive reaches its fully-advanced or fully-retracted position. (Col 2, line 67 to col. 3, line 4). Niehoff discloses allowing the operator to adjust the rate at which the plunger drive moves or accelerates and essentially moving the syringe based on a "locked mode" or by operator manual control (see Col. 5, lines 1- 36). Further, Niehoff discloses storing an offset value representing the length of the extender to apply to the plunger drive jaw. Therefore, Niehoff is directed to controlling the plunger in limited ways based on the operator input, but does not disclose either automatically advancing the piston based on actual sensing of the presence of the syringe.

Accordingly, Neihoff does not disclose any "advancing the piston to prime the syringe and a tube connected to the syringe" of Claims 1 and 11 or "advancing the piston to prime the fluid path" of Claim 8, and thus Applicants' invention is not anticipated by Neihoff.

Claims 2-3, 5, 6, 10 and 14-17 depend from Claims 1, 8, and 11 respectively, which as discussed herein is believed to be allowable. Thus, Claims 2-3, 5, 6, 10 and 14-17 are also believed to be allowable. Accordingly, reconsideration is respectfully requested.

2. Claims 1-3 and 5-17 stand rejected under 35 USC 102(b) as being anticipated by Battiato.

As discussed above, Applicants invention includes "advancing the piston to prime the syringe and a tube connected to the syringe" or "advancing the piston to prime the fluid path."

The Office Action alleges that: [Battiato] teaches a method of using an injector (22) with a syringe (38) with a plunger (31) and piston (62) comprising operating a piston in forward and reverse directions either automatically or by hand (with 29) to load, inject and eliminate air from the syringe.

However, Battiato discloses a "hand-operated motion of the plunger drive ram in either the forward or reverse direction, allowing the operator to fill the syringe and remove air from the syringe after initial filling. A wide range of movement speeds can be generated with the hand-operated movement control, permitting rapid filling of the syringe. While the power head 22 is in regions 1, 2a or 2b, however, programmed injections are inhibited; thus, the operator cannot initiate injection of a subject according to a pre-programmed injection protocol while the power head 22 is in an upright position." (col. 19, line 61 to col 20, line 3) Battiato does not disclose any priming of the syringe or tube connected to the syringe. Therefore, Battiato does not disclose every element of Applicants' inventions of claims 1, 8 and 11, including "advancing the piston to prime the syringe and a tube connected to the syringe" or "advancing the piston to prime the fluid path. Thus, Claims 1, 8 and 11 are believed to be allowable.

Claims 2-3, 5, 6, 10 and 14-17 depend from Claims 1, 8, and 11 respectively, which as discussed herein is believed to be allowable. Thus, Claims 2-3, 5, 6, 10 and 14-17 are also believed to be allowable. Accordingly, reconsideration is respectfully requested.

Double Patenting

Claim 12 has been objected to under 37 CFR 1.755 as being a substantial duplicate of Claim 1. Claim 12 has been canceled. Accordingly the objection is moot.

In view of the above amendments and remarks, Applicants respectfully requests that the Examiner withdraw the rejections of the claims, indicate the allowability of the claims and arrange for an official Notice of Allowance to be issued in due course.

Respectfully submitted,

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